PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
MTX_102		
International application No.	International filing date (*day/month/year*)	Priority Date (*day/month/year*)
PCT/IN 2003/000294	2 September 2003 (02.09.2003)	2 September 2002 (02.09.2002)
International Patent Classification (IPC) or national classification and IPC		
IPC[7]: A61K 31/421, 9/14, 45/06		
Applicant		
SUN PHARMACEUTICAL INDUSTRIES LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examination Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

   I. ☒ Basis of the opinion

   II. ☐ Priority

   III. ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

   IV. ☐ Lack of unity of invention

   V. ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI. ☒ Certain documents cited

   VII. ☒ Certain defects in the international application

   VIII. ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
08.03.2004	3 January 2005 (03.01.2005)
Name and mailing address of the IPEA/AT Austrian Patent Office Dresdner Straße 87 A-1200 Vienna Facsimile No. 1/53424/200	Authorized officer KRENN M. Telephone No. 1/53424/435

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International application No.
PCT/IN 2003/000294

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.

☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____.

☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____.

☐ the claims, Nos. _____.

☐ the drawings, sheets/fig _____.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as „originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 19-22,25,26.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 19-22,25,26 are so unclear that no meaningful opinion could be formed *(specify)*:

Characterization of pharmaceutical dosage forms by their modes of administration is insufficient; thus claims 19-22 resp. the dependent claims 25 and 26 were not considered in establishing the present examination.

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	8-14	YES
	Claims	1-7,15-18,23,24	NO
Inventive step (IS)	Claims	----	YES
	Claims	1-18,23,24	NO
Industrial applicability (IA)	Claims	1-18,23,24	YES
	Claims	----	NO

Citations and explanations (Rule 70.7)

As the applicant has abstained from responding to the Written Opinion, the objections raised therein are still maintained.
Consequently, only claims 8-14 show the required novelty, whereas claims 1-7,15-18,23 and 24 are not considered to be new.
Inventiveness is denied for all examined claims, namely claims 1-18,23 and 24.

Industrial applicability is given for claims 1-18,23 and 24.

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VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
DE 10153078 A1	22.5.2003	30.10.2001	

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)

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VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The characterizing parts of claims 1,2,5 and 8 were not considered in establishing the present report, because they include insufficiently defined formulations, namely "..pharmaceutical composition has enhanced oral bioavailability." (claims 1,8), "..a pharmaceutically acceptable solubility-improved form." (claim 2) and "..high-energy crystalline form of metaxalone." (claim 5).